POSTER

TCT-152

Restenosis Following Distal Left Main Percutaneous Coronary Intervention With A 2 Stent-technique: Incidence, Immediate And Long-term Outcomes

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Background: Distal left main coronary artery (LMCA) stenosis is a technical challenge for interventional cardiologists that can be approached by different strategies (1 vs. 2 stent). Despite observational studies reporting a better clinical outcome of 1 stent vs. 2 stent techniques, there are limited data regarding the incidence, management and outcomes of restenosis following distal LMCA treatment with 2 drug-eluting stents (DES).
Methods: Retrospective cohort analysis of consecutive patients undergoing PCI with DES implantation for distal LMCA between April 2002 and December 2008. The aim of this study was to identify the incidence of restenosis following distal LMCA treated with 2 DES and evaluate the immediate and long-term outcomes.
Results: We identified 234 patients who underwent PCI with DES for distal LMCA stenosis. Of these, 140 (59%) were treated with a 2-stent technique: 63 (45%) Crush, 41 (29%) Culotte, 17 (12%) T-stenting. The mean age was 65±10.3 years, 119 (85%) were male and 35 (25%) were diabetics. Final kissing balloon inflation was performed in 113 (81%) patients. Angiographic follow-up was obtained in 102 pts (73%). In-stent restenosis (ISR) was found in 20/102 patients (20%). Of these 12/20 (60%) were focal and 8/20 (40%) were diffuse. The ISR site was: SB in 8 (40%), MB in 5 (25%), both branches in 7 (35%). Focal ISR was treated with POBA in 7/12 cases (58%) and with DES implantation in 5/12 (42%) cases. Of the 8 diffuse ISR, 5 (62%) underwent CABG while 3 (38%) were treated with re-PCI. No peri-procedural death, MI or ST were reported during restenosis treatment with PCI. At a median follow up of 2.4 years (IQR 1-5.7) 5 patients (20%) in the ISR cohort died (3 cardiac deaths). No MI, TLR or definite/probable ST were reported in the ISR cohort. However, in the overall cohort, 2 (1.4%) patients suffered a definite/probable ST, of whom 1 died and 1 survived the event following emergent PCI.
Conclusions: The incidence of ISR following 2-DES implantation for distal LMCA is acceptable and can be managed in most of cases with re-PCI that is associated with favorable immediate and long term outcomes.

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Long-term Outcomes of Sirolimus-Eluting Stents versus Paclitaxel-Eluting Stents in Unprotected Left Main Coronary Artery Bifurcation Lesions

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Background: The treatment of unprotected left main coronary artery (uLMCA) bifurcation lesions remains challenging. We compared the safety and efficacy of sirolimus-eluting stent (SES) and paclitaxel-eluting stent (PES) implantation for the treatment of uLMCA bifurcation lesions.
Methods: One hundred fifteen patients who underwent stent implantation using a provisional T-stenting technique with SES or PES for uLMCA bifurcation lesions were enrolled. A major adverse cardiac event (MACE) was defined as a composite of cardiac death, myocardial infarction or target lesion revascularization.
Results: Ninety-four patients were treated with SES and 21 patients with PES. Baseline characteristics were similar between the two groups. Angiographic follow-up was performed in 99 (86%) patients. Late loss in the LMCA to the left anterior descending coronary artery was significantly lower in the SES group than in the PES group (0.28±0.54 mm versus 1.03±0.45 mm, p<0.001). One case of stent thrombosis occurred in the SES group. During follow-up with a median of 712 days, the SES group had a lower MACE compared with the PES group (10.6% versus 28.6%, p=0.032). Cox proportional hazards models including age, sex, diabetes, acute coronary syndrome, true bifurcation, stenting strategy, and type of drug-eluting stent used (SES versus PES) demonstrated that stent type was the only predictor of MACE (HR of PES versus SES 3.88, 95% CI 1.29 - 11.67, p=0.016).

Clinical outcomes in the two patient groups

	All patients (n = 115)	SES (n = 94)	PES (n = 21)	p Value
Cardiac death, n (%)	3 (3%)	2 (2%)	1 (5%)	0.50
MI, n (%)	2 (2%)	1 (1%)	1 (5%)	0.20
TLR, total, n (%)	11 (10%)	7 (7%)	4 (19%)	0.11
TLR in the LMCA to LAD, n (%)	2 (2%)	1 (1%)	1 (5%)	0.33
TLR in the LCX, n (%)	9 (8%)	6 (6%)	3 (14%)	0.36
Major adverse cardiac events, n (%)	16 (14%)	10 (11%)	6 (29%)	0.032
Stent thrombosis, n (%)	1 (1%)	1 (1%)	0 (0%)	>0.99
SES, sirolimus-eluting stent; PES, paclitaxel-eluting stent				

Conclusions: According to the results of the present study, SES implantation appears to yield better long-term outcomes than PES for the treatment of uLMCA bifurcation lesions.

TCT-154

Prognostic Impact of Total Chronic Occlusion of The Right Coronary Artery in Patients Treated with Drug-Eluting stent for Unprotected Left Main Disease

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Background: Data from registries have shown a spread increase in drug-eluting stent implantation (DES) for unprotected left main disease (ULMD). No data exist about the clinical impact of total chronic occlusion of the right coronary artery (RCA-CTO) in patients treated with DES for ULMD.
Methods: Data collected in the Florence Registry from 2005 to 2009 including all patients admitted to Florence hospital with ULMD undergoing DES implantation. Only patients with ST-T elevation acute myocardial infarction were excluded from the analysis. There were no angiographic exclusion criteria. Primary end point was cardiac mortality at long term follow-up. Survival curves were generated using the Kaplan-Meier method, and the difference between groups was assessed by log rank test.
Results: From 2005 to 2009, n= 330 patients with ULMD underwent DES implantation. Out of these n=78 (24%) had RCA-CTO. Patients with RCA-CTO compared to patients without RCA-CTO had a higher Euroscore (20 ± 22 vs 13 ± 17; p =.003, Euroscore ≥ 6: 68% vs 51%; p=.009) and a lower left ventricular ejection fraction (39 ± 14% vs 47 ± 12%; p <.001). There were no other clinical, angiographic or procedural differences between patients with RCA-CTO and patients without RCA-CTO (mean age 71 ± 11 vs 72 ± 9, diabetes 35% vs 28%, previous myocardial infarction 31% vs 23%, admission for acute coronary syndrome 80% vs 69%, distal left main location 92% vs 84%, multiple stent implantation 32% vs 38%). Patients without RCA-CTO compared to the other group underwent a significantly higher completeness of coronary artery revascularization (89% vs 44%, p <.001). There were 3 procedural deaths (0.9%), 2 of these in patients with RCA-CTO. Mean clinical F-U for the entire cohort of patients was 678 ± 559 days. By Kaplan-Meier estimation long-term cardiac mortality was significantly higher in patients with angiographic evidence of RCA-CTO compared to patients without RCA-CTO: 76 ± 7 % vs 89 ± 3%, p =.003.
Conclusion: Patients with ULMD treated with DES and RCA-CTO had a long-term cardiac mortality compared to patients without RCA-CTO.

TCT-155

Clinical Benefit of Use of Kissing Balloon Inflation and Non-Compliant Balloon in the Crush Technique for Bifurcation Coronary Lesions

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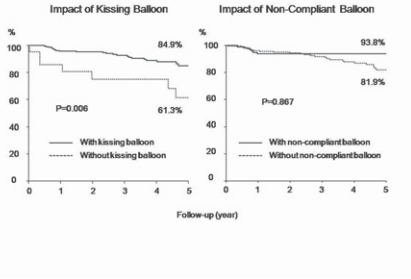
Background: Although the final kissing balloon inflation is recommended as a mandatory step in the Crush technique with drug-eluting stent (DES) for bifurcation coronary lesions, its benefit using non-compliant balloon has still not been determined well.
Methods: A total of 384 patients who underwent DES implantation with the Crush technique for bifurcation coronary lesions were enrolled. Patients who were treated with primary stenting for acute myocardial infarction or were followed for less than 6 months were excluded. In all patients, major adverse cardiac events (MACE) comprising all-cause deaths, spontaneous myocardial infarction, and target lesion revascularization (TLR) were evaluated.
Results: Final kissing balloon inflation was successfully performed in 363 (94.5%) lesions and non-compliant balloon in 177 (46.1%) lesions. For the follow-up period (median 23.6 months; interquartile range 12.3, 52.5), the MACE-free survival was lower in patients with kissing than those without kissing, but was not different between patients using non-compliant versus compliant balloons (Figure). In multivariate Cox models, a failure of final kissing inflation was significantly associated with long-term MACE (hazard ratio 3.00; 95% confidence interval 1.29, 6.97; p=0.010).



Conclusion: Final kissing balloon inflation in the Crush technique using DES reduces the risk of long-term MACE. But, clinical benefit of non-compliant balloon in improving clinical outcomes needs to be further estimated in large-scale studies.

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Coronary Bifurcation Lesions Treated with the Novel Polymer-Free Dedicated Bifurcation Paclitaxel-Eluting Stent (Nile Pax) - Procedural and 30-Day Results of the Prospective, Multicenter BIPAX Clinical Trial

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Background: The Nile PAX® dedicated drug-eluting stent (Minvasys SAS, France) is a novel technology designed for treatment of bifurcation lesions that incorporates the following components: 1. a cobalt-chromium alloy designed to optimize scaffold of the bifurcation carina with maintenance of side branch (SB) access without need for rewiring (Nile CroCo® platform, Minvasys SAS, France); 2. a non-polymeric coating (PAX) technology; and 3. a potent antiproliferative agent (paclitaxel).
Methods: From Dec/08 to Mar/09, a total of 102 pts with single bifurcation lesion were prospectively enrolled in this non-randomized, multicenter (9 sites in Europe/South America) study. Lesion criteria were vessel size 2.5-3.5mm in the parent vessel (PV) and 2.0-3.0mm in the SB, and lesion length <14mm in the PV. Clinical follow-up was scheduled at 1, 3, 6, 9 and 12 months, and yearly up to 5 years. Angiographic follow-up was scheduled at 8 months. We report the procedural and 30-day outcomes.

All clinical events were adjudicated by an independent clinical events committee.
Results: Baseline characteristics included mean age of 63 years, 29% diabetes, 16 previous MI, and 40% previous intervention. The LAD/Dg was the most prevalent lesion location (75%), and 60% had significant involvement of the SB. Regarding procedure, PV was predilated in 97%; the study stent was successfully attempted and implanted in 99%. Overall, 25% of SB received an additional stent; and 94% had final kissing-balloon inflation. By QCA, baseline mean lesion length, vessel diameter and % diameter stenosis were: 10.9mm, 2.99mm and 72% in the PV, and 4.1mm, 2.28mm, and 38% in the SB, respectively; angiographic success (residual stenosis <50%, final TIMI 3 flow, and absence of dissection) was achieved in 98%. There was only 1 MACE during hospitalization, which was adjudicated as a non-Q myocardial infarction during hospitalization, and no additional adverse events were reported up to 30 days follow-up.
Conclusions: The novel Nile PAX dedicated bifurcation polymer-free technology demonstrated excellent performance in the treatment of complex bifurcation lesions, including high procedural success and no events from discharge to 30 days follow-up. Longer term follow-up is warranted.

CAD Outcomes

(Abstract Nos 157-195)

TCT-157

SYNTAX Score Reproducibility and Agreement Between Interventional Cardiologists and Core Laboratory Technician Measurements

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Background: In the SYNTAX trial the SYNTAX score was shown to be a useful prognostic tool to risk stratify pts with complex CAD. Since this score is calculated by visual lesion assessment, interobserver variability may affect its reproducibility. An interobserver agreement Kappa of 0.52 among the highly trained SYNTAX core lab (CL) technicians has been published. We sought to assess the SYNTAX score interobserver variability among a group of interventional cardiologists (ICs) and technicians from a different but highly experienced CL (Cardiovascular Research Foundation, NY).
Methods: After basic training from the SYNTAX score website (www.syntaxscore.com), 3 ICs and 4 CL technicians all working individually assessed the SYNTAX score from 30 pts with multivessel disease. After the ICs underwent a 2nd extensive training session with the CL, the SYNTAX score from 50 additional angiograms was assessed, again independently. Interobserver Fleiss Kappa statistic values (tertile partitioning) were determined.
Results: The CL interobserver variability from both periods was very low (high Kappa). The IC interobserver variability was high initially but improved after advanced training. Compared to CL, ICs underscored the number of lesions (p<0.001), bifurcations (p<0.001), and the presence of small vessel ds. (p<0.0001), resulting in a lower SYNTAX score (mean [95%CI] difference = 7.5 [5.5, 9.5], p<0.001).

Level of agreement of the SYNTAX score before and after a training session		
Core Laboratory Technicians		
	30 cases after basic training	50 cases after advanced training
	Kappa ± SD	Kappa ± SD
SYNTAX score (tertile)	**0.76 ± 0.04**	**0.74 ± 0.04**
Number of lesions	0.70 ± 0.03	0.77 ± 0.02
Presence of severe calcification	0.86 ± 0.07	0.84 ± 0.06
Length >20 cm	0.61 ± 0.07	0.84 ± 0.06
Bifurcation/trifurcation	0.47 ± 0.03	0.56 ± 0.02
Sum of lesions	0.80 ± 0.05	0.75 ± 0.04
Small vessel disease	0.66 ± 0.03	0.60 ± 0.03
Total occlusion present	0.96 ± 0.07	1.00 ± 0.05
Interventional Cardiologist Group		
	30 cases after basic training	50 cases after advanced training
	Kappa ± SD	Kappa ± SD
SYNTAX score (tertile)	**0.32 ± 0.07**	**0.57 ± 0.07**
Number of lesions	0.26 ± 0.05	0.65 ± 0.05
Presence of severe calcification	0.23 ± 0.10	0.57 ± 0.08
Length >20 cm	0.48 ± 0.10	0.65 ± 0.08
Bifurcation/trifurcation	0.13 ± 0.05	0.49 ± 0.05
Sum of lesions	0.33 ± 0.08	0.56 ± 0.07
Small vessel disease	0.21 ± 0.06	0.30 ± 0.05
Total occlusion present	0.81 ± 0.10	0.96 ± 0.08

Conclusion: Reproducible SYNTAX score measurements were quickly achieved by an experienced CL. In contrast, there was high interobserver variability in the SYNTAX score among ICs after the basic tutorial, which was substantially improved after further training with the CL, although differences still remained in interpretation of several lesion types. These findings have important implications for adoption of SYNTAX score methodology in routine practice.

TCT-158

Correlates and Consequences of Gastrointestinal Bleeding Complicating Percutaneous Coronary Intervention

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Background: Gastrointestinal bleeding (GIB) complicating percutaneous coronary intervention (PCI) results in high mortality, but clinical factors associated with long-term outcomes are poorly understood.
Methods: 20621 patients undergoing PCI from January 2000 through January 2010 were retrospectively analyzed for the occurrence of in-hospital GIB. Multivariable logistic regression and Cox proportional hazards regression were utilized to identify predictors of in-hospital GIB and 30-day mortality. Landmark analysis of patients surviving to hospital discharge was performed to assess the impact of GIB upon 1-year major adverse cardiac events (MACE).
Results: 147 (0.72%) patients were identified with in-hospital GIB. Variables associated with an increased risk of GIB included older age, shock, acute myocardial infarction (MI), chronic renal insufficiency, lower baseline hematocrit, and glycoprotein IIb/IIIa inhibitors; bivalirudin decreased the risk. (Table) The unadjusted 30-day mortality rate for patients with GIB was 20.5%, compared to 2.4% for patients without GIB. After multivariable adjustment, GIB and shock (and an interaction between the two) were the most important correlates of 30-day mortality. In the population surviving to discharge, however, GIB was not associated with adjusted mortality or MACE.

	Odds Ratio	95% Confidence Interval	p value
Age (per 10 years)	1.34	1.13-1.58	0.001
Shock	4.58	2.74-7.67	<0.001
Acute MI	2.43	1.58-3.74	<0.001
CRI	2.49	1.66-3.73	<0.001
Baseline hematocrit (per 5%)	0.64	0.56-0.72	<0.001
Glycoprotein IIb/IIIa inhibitor	1.85	1.17-2.91	0.008
Bivalirudin	0.58	0.36-0.94	0.03
Heparin	0.79	0.50-1.25	0.32
Thrombolytics	0.74	0.36-1.55	0.43

Conclusions: GIB complicating PCI has a dramatic impact upon 30-day mortality. Decreased rates of bleeding observed with bivalirudin suggest it should be preferred in patients at higher risk of GIB.

TCT-159

Predictors of Stent Thrombosis In Real World Patients From XIENCE V® USA Study

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Background: The safety of XIENCE V® everolimus-eluting coronary stents (XIENCE V, Abbott Vascular) has been demonstrated with low stent thrombosis (ST) rates in the randomized SPIRIT trials and the COMPARE trial. XIENCE V USA is a prospective, multicenter, post-approval single-arm study designed to examine the safety and efficacy of XIENCE V in an all-inclusive, consecutively-enrolled population from real-world clinical settings. To better understand the patient and lesion characteristics that predict ST in contemporary practice with XIENCE V, 1-year data from the 5054 patients enrolled in the XIENCE V USA study were analyzed.
Methods: Patients were enrolled at the initiation of percutaneous coronary intervention with no inclusion/exclusion criteria beyond the use of only XIENCE V during the index procedure. Academic Research Consortium (ARC) defined definite/probable ST was adjudicated by an independent Clinical Events Committee. Demographic, clinical, and procedural variables were assessed using multivariable, stepwise, logistic regression analysis with independent variables entered into the model at the 0.20 significance level.
Results: In this real-world population of ~5000 patients, XIENCE V USA demonstrated a low overall rate of 1-year ST (ARC definite/probable, 0.86%) and late ST (0.39%). Dual antiplatelet therapy (DAPT) compliance at 1 year was 79.4% in this study. The independent predictors of ARC definite/probable ST at 1 year by multivariable analysis included restenosis lesions (OR: 5.61 [2.11, 14.92], p=0.0006), total length of implanted stents (OR: 1.03 [1.00, 1.05], p=0.0175), and renal insufficiency (OR: 3.48 [1.21, 10.05], p=0.0210). Vessel size, B2/C lesion type, diabetes, and the presence of acute myocardial infarction at the time of index procedure were not independently associated with ST in XIENCE V USA.
Conclusion: In this large, real-world XIENCE V-treated population, overall 1-year ST rate was low (0.86%), despite low DAPT compliance. Predictors for overall ST include restenosis lesions, stent length and renal insufficiency. A comprehensive multivariable regression analysis of ST, including late and early ST, will also be provided.

TCT-160

Temporal Trends in Gastrointestinal Bleeding with Percutaneous Coronary Intervention in the US: Findings from the Nationwide Inpatient Sample

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Background: Multiple clinical trials demonstrate that gastrointestinal bleeding (GIB) with percutaneous coronary intervention (PCI) is associated with adverse events and increased mortality. However, little data exist of any temporal trends in GIB events as new pharmacological and technical developments have occurred with PCI. We conducted a retrospective study to evaluate the contemporary temporal trends in GIB events with PCI.
Methods: The Nationwide Inpatient Sample, the largest all-payer US inpatient care database was analyzed from 1998 to 2006. There were 1.216,739 PCI procedures with ST and non-ST elevation myocardial infarction and CAD diagnoses (elective PCI). GIB was defined as any active bleeding from the upper or lower GI tract. In-hospital mortality, length of stay (LOS), cost of hospitalization, age, and gender were analyzed.
All tests were 2-tailed, and a *P* value of less than 0.05 was considered significant. The chi-square test was used for categorical variables and t-test for continuous variables.
Results: Patients with GIB tended to be older (mean age 64 vs. 70, p <0.000), having a longer LOS (2.78 vs. 7.61 days, p <0.000), and increased cost of hospitalization ($36, 758 vs. $60,094, p<0.000).

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